

K090902

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510(k) Summary – K090902

This summary of safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: June 26, 2009

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1. Submitter:

Submitted by:

TransEnterix, Inc.
3908 Patriot Drive, Suite 170
Durham, NC 27703

TEL: 919-541-9977

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Contact:

Tammy Carrea
Director, Regulatory Affairs and Quality Assurance

2. Device:

Propriety Name

SPIDER™ Single Port Surgical Device

Common Name

Laparoscopic instrument and accessory

Classification Name:

Endoscope and accessories

Classification:

Class II 21 CFR 876.1500

Product Code:

GCJ

3. Predicate Device:

Covidien, SILS Port – K082619

Endopath III Bladeless Trocar – K032676

4. Description:

The SPIDER™ is a single port, single incision device to facilitate multi-instrument access during laparoscopic surgical procedures.

Following a Hasson cut down incision, the multi-channel cannula is inserted through a small abdominal incision. The channels are deployed allowing laparoscopic instruments to pass through each channel into the abdomen to perform laparoscopic surgery.

Two channels known as IDTs (Instrument Delivery Tubes) are positioned east to west and include extended lumens to facilitate manipulation of flexible surgical instruments, enabling control of the instruments over extended distances. These 2 IDTs are flexible and allow for x, y, and z motion for a multidirectional approach

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of the surgical field, mimicking the approach of standard laparoscopic surgery. Two (2) rigid channels, north to south, can accommodate an endoscope or a rigid surgical instrument. The device includes ports for insufflation or smoke evacuation. Pneumoperitoneum is maintained in the abdomen during the surgical procedure. The single use SPIDER™ device is provided pre-sterilized and is a single use device.

5. Indications for Use:

The SPIDER™ (Single Port Instrument Delivery Extended Reach) is intended to establish a path of entry for laparoscopic instruments for use during minimally invasive abdominal laparoscopic surgery.

6. Comparison of Technological Characteristics with Predicate:

The SPIDER™ Device has the same intended use and function of other currently marketed single port access devices and single port trocars in that it is intended to establish a path of entry for laparoscopic instruments in minimally invasive abdominal procedures. Like the single port predicates it achieves this function via a single port and single incision. The device has the same main port and channel dimensions and similarly employs a similar number of rigid and flexible ports like the predicates. Like the predicate devices it includes valves to maintain pneumoperitoneum and insufflation ports and stopcocks to achieve insufflation and smoke evacuation. Similar to the predicate devices it is provided pre-sterilized, is disposable, and is a single use device, the same as other predicate devices.

It incorporates the same design features as the predicates to facilitate minimally invasive surgical procedures. It has multiple channels to facilitate introduction of numerous surgical instruments. It may be inserted using a Hasson technique under direct visualization. It has IDTs to allow placement, control and manipulation of rigid and flexible surgical instruments.

The IDTs, while longer than the channels of the predicate devices, are not longer than the effective length of surgical instruments and are presented and positioned within the surgical space in a similar manner. The IDTs are able to achieve triangulation in a manner similar to that of standard multi-port laparoscopic equipment.

The SPIDER™ device also includes a Support Arm accessory. The support arm is provided to mount and stabilize the device. The support arm has been tested for mechanical stability, strength, and repeated use and found to be adequate to stabilize and maintain the SPIDER™ device in a fixed position during surgical procedures.

7. Performance Data:

Verification and validation studies were conducted for the SPIDER™ to demonstrate biocompatibility, sterility, and functionality. Pre-clinical studies were conducted to demonstrate equivalency to the medical effect achieved with standard multiple incision laparoscopic surgery and to validate the intended use of the device.

The Support Arm was tested to validate cleaning and autoclaving cycles. The Support Arm was also tested for retention strength, mechanical strength under simulated use, and functionality following repeated use.

Any technological differences between the SPIDER™ device and the predicates have been mitigated via verification and validation testing. Thus the SPIDER™ device does not introduce any new issues of safety or effectiveness compared to other similar single port access devices currently marketed.

8. Conclusion:

The conclusion drawn from the test data is that the SPIDER™ device is as safe and effective as the predicate devices, performs similarly to other legally marketed predicate devices for laparoscopic surgery, and does not raise any new issues of safety or effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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TransEnterix, Inc.
% Ms. Tammy B. Carrea
Director Regulatory Affairs
and Quality Assurance
3908 Patriot Drive, Suite 170
Durham, North Carolina 27703

Re: K090902

Trade/Device Name: SPIDER™ (Single Port Instrument Delivery Extended Reach)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: June 27, 2009
Received: June 30, 2009

Dear Carrea:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Mark N. Melkerson', is written over the typed name.

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K090902

510(k) No.

If known

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Indications For Use Statement

Device Name: SPIDER™ (Single Port Instrument Delivery Extended Reach)

Indications For Use:

The SPIDER™ (Single Port Instrument Delivery Extended Reach) is intended to establish a path of entry for laparoscopic instruments for use during minimally invasive abdominal laparoscopic surgery.

Prescription Use

x

AND/OR

Over-the-Counter Use

(Per 21 CFR 801 Subpart D)

(Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

Michael P. Graham for MxM

(Division Sign-Off)
Concurrent Office of CDHR, Office of Device Evaluation (ODE)

Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number

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